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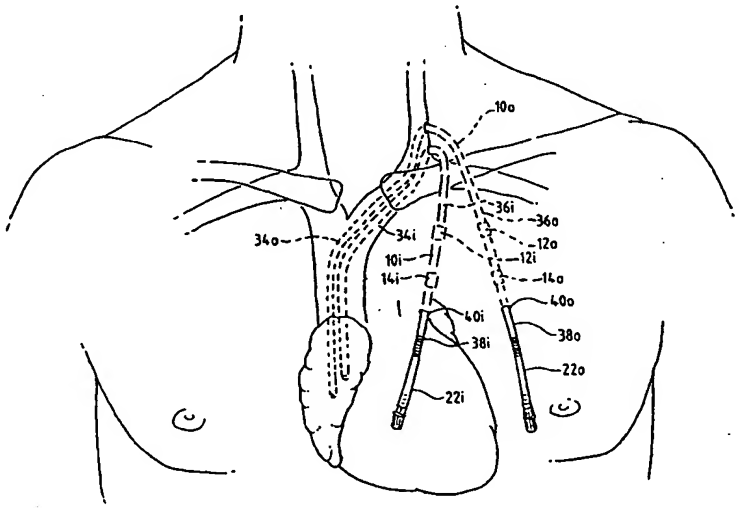

(57) Abstract

This invention is a single lumen, flexible, implanted catheter for permanent access to the vascular system of a patient. The catheter has proximal and distal ends (22i/o) (34i/o), respectively), being free of side holes adjacent to the distal end. Thus, clotting is reduced. The catheter carries at least two spaced tissue attachment cuffs (12i/o) (14i/o) adjacent to the proximal end, the cuffs being of the type that provides substantially immoveable attachment of the catheter to surrounding tissue. This provides better resistance to infection, reduces tunnel wall, and vein wall tissue injury. Also, preferably the catheter has an outer diameter of essentially no more than 4.5 mm, which is less than the outer diameter of dual lumen catheters, which results in reduced tissue injury resulting from the implanted catheter, and less infection.

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DOUBLE CUFFED, SINGLE LUMEN, CENTRAL-VEIN CATHETERS

TECHNICAL FIELD

Jugular and subclavian single lumen, double cuffed catheters are intended as a permanent blood access for fluid delivery into the blood stream or egress of blood. Although these catheters may be used for various purposes including treatment of acute renal failure, they are essentially intended for treatment of chronic renal failure. This invention decreases the rates of thrombosis and infections, and prolongs the overall survival of the catheters.

PRIOR ART

Historical Perspective

Cannulation of femoral vessels for hemodialysis was introduced by Shaldon et al. in 1961 (Shaldon S, Chiandussi L, Briggs B: Hemodialysis by percutaneous catheterization of the femoral artery and vein with regional heparinization. Lancet 1961; 2: 857 - 859). Shaldon used Teflon® tubings for femoral artery and vein catheterization for repeated hemodialysis. Shaldon gradually improved his method and in 1964 used Teflon® tubing with silicone rubber extensions for venovenous catheterization of femoral veins (Shaldon S: Percutaneous vessel catheterization for hemodialysis. ASAIO J 1994; 40: 17 - 19).

Percutaneous subclavian vein catheterization was introduced by Aubaniac in 1952 (Aubaniac R: L'injection intraveneuse sous clavière. Presse Med 1952; 60: 1456 -

1461) and gained popularity after it was shown to be the most convenient site of catheter insertion for central venous pressure monitoring (Wilson JN, Grow JB, Demong CV, Prevedel AE, Owens JC: Central venous pressure monitoring in optimal blood volume maintenance. Arch Surg 1962; 85: 563 - 578). In 1967 Christensen et al. (Christensen KH, Nerstrøm B, Baden H: Complications of percutaneous catheterizations of the subclavian vein in 129 cases. (Acta Chir Scand 1967; 133: 615 - 620) They reported their experience with 129 subclavian vein catheterizations and reviewed the results of more than 1,350 subclavian vein cannulations reported in the literature. The majority of the catheters remained in place for less than five days. Pneumothorax (29 cases) and arterial puncture (13 cases) were the most common complications followed by wrong position (12 cases), hemothorax (5 cases), subcutaneous hematoma (5 cases), infection with sepsis (4 cases), nonfatal air insufflation (4 cases), and nerve lesion (1 case). The authors recommended the method as valuable because it was associated with low complication rates. On the contrary, Shapira and Stern (Shapira M, Stern WZ: Hazards of subclavian vein cannulation for central venous pressure monitoring, (JAMA 1967; 201: 111 - 113) based on their experience and that of others, recommended this technique be abandoned. Instead, they favored cannulation through the external jugular vein, the method described a year earlier by Rams, Daicoff and Moulder. (Rams JJ, Daicoff GR, Moulder PV: A Simple method for central venous pressure measurements. Arch Surg 1966; 92:886). No complications were reported in 275 cannulations using this method.

Subclavian vein cannulation for hemodialysis was first described by Erben et al. in 1969 (Erben J, Kvasnicka J, Bastecky J, Vortel V: Experience with routine use of subclavian vein cannulation in hemodialysis. Proc Eur Dial Transpl Assoc 1969; 6: 59 - 64). These authors used two single-lumen catheters inserted into both subclavian veins (59 cases), the same subclavian vein (14 cases), or one inserted in a subclavian vein and the other in a femoral vein (28 cases). All catheters were inserted through the infraclavicular route using the Seldinger Technique (Seldinger SI: Catheter replacement of needle in percutaneous arteriography; new technique. Acta Radiol 1953; 39: 368 - 376) method of insertion. The catheters were left in place for up to one month. De Cubber et al. (De Cubber A, De Wolf C, Lameire N, Schurgers M, Ringoir S: Single needle hemodialysis with the double headpump via the subclavian vein. Dialysis & Transplantation 1978; 7: 1261- 1263) and Uldall et al. (Uldall PR, Dyck RF, Woods F, Merchant N, Martin GS, Cardella CJ, Sutton D, de Veber GA: A subclavian cannula for temporary vascular access for hemodialysis or plasmapheresis. Dialysis & Transplantation 1979; 8: 963 - 968) used single-lumen subclavian cannulae for repeated dialysis leaving them in place for prolonged periods. Both groups employed the Seldinger method of insertion and used single-needle dialysis.

Although jugular vein cannulation has been practiced by generations of pediatricians, catheterization of these veins for central pressure monitoring and fluid delivery was introduced in adults in the 1960s. Internal jugular vein catheterization

through the anterior approach was described by Hermosura et al in 1966 (Hermosura B, Vanags L, Dickey MW: Measurement of pressure during intravenous therapy. JAMA 1966; 195: 321 - 321). In the same year, external jugular vein cannulation was introduced by Rams et al (Rams JJ, Daicoff GR, Moulder PV: A Simple method for central venous pressure measurements. Arch Surg 1966; 92:886).

In the early 1980s, two lumen catheters were introduced because the time of vessel cannulation could be reduced by half. Initially, stiff tetrafluoroethylene (Bregman H, Hoover M: The double-lumen subclavian cannula - a unique concept in vascular access. Dialysis & Transplantation 1982; 11:1065-1070) or polyurethane (Graber DA, Dinerstein C: The Quinton-Mahurkar dual lumen subclavian catheter - preliminary clinical evaluation. Dialysis & Transplantation 1983; 12: 847 - 850) catheters were used. The first catheter was developed by Vas-Cath of Canada and consisted of 17 cm long "arterial cannula" with six spirally placed side holes near the tip, and a 19 cm long inner, coaxially placed "venous cannula". The venous cannula was replaced for each dialysis. The second catheter was developed by Quinton Instruments in Seattle, WA, consisting of a septated dual-lumen design. Both companies improved designs, and their catheters are widely used for short-term therapy.

A soft, silicone rubber catheter for long-term dialysis was used first in infants and small children in the early 1980s (Mahan JD Jr, Mauer SM, Nevins TE: The Hickman catheter: a new hemodialysis access device for infants and small children. Kidney Int 1983; 24: 694 -

697). The authors reported experience with 26 catheters inserted through the left or right external or internal jugular veins into the right atrium or superior vena cava. A single-needle dialysis system was used and blood flows up to 70 mL/min were achieved. Low complication rates were reported, and the longest catheter survival was over 389 days. Single-lumen, soft, right atrial catheters were used also in adults (Francis D, Ward MK, Taylor RMR: Right atrial catheters for long term vascular access in hemodialysis patients. Lancet 1982; 2: 301 - 302). Double-lumen, soft, silicone rubber catheters were used for hyperalimentation at that time (Sanders JE, Hickman RO, Aker S, Hersman J, Buckner CD: Experience with double-lumen right atrial catheter. JPEN 1982; 6: 95 - 99). A few years later double-lumen, silicone rubber, catheters were provided with a single cuff and used for acute and/or chronic hemodialysis. Schanzer et al. (Schanzer H, Kalan S, Bosch J, Glabman S, Burrows L: Double-lumen, silicone rubber, indwelling venous catheters: A new modality for angioacess. Arch Surg 1986; 121: 229 - 232) used 3 types of catheters: Raaf (internal diameter 1 mm); Hickman (internal diameter 1.6 mm); and HemoCath (internal diameter 2 mm).

In the late 1980s, a soft, silicone rubber, double-lumen catheter (PermCath®) was used in adults as means of "prolonged" or short-term hemodialysis access or when other forms of access were not possible. (Schwab SJ, Buller GL, McCann RL, Bollinger RR, Stickel DL: Prospective evaluation of a Dacron cuffed hemodialysis catheter for prolonged use. Am J Kidney Dis 1988; 11: 166 - 169. Moss AH, McLaughlin MM, Lempert

KD, Holley JL: Use of a silicone catheter with a Dacron cuff for dialysis short-term vascular access. Am J Kidney Dis 1988; 12: 492 - 498. Carbone V: Hemodialysis using the PermCath™ double lumen catheter. ANNA Journal 1988; 15: 171 - 173, 193.)

Currently available catheters

There are numerous manufacturers producing various catheters and the line of products is changing every year. An extensive review of all available catheters for acute and chronic hemodialysis was published in 1995 (Twardowski ZJ: Percutaneous blood access for hemodialysis. Seminars in Dialysis 1995; 8: 175-186). Here I concentrated on single and dual lumen catheters for chronic hemodialysis.

Dual lumen catheters

These catheters are made of silicone rubber or polyurethane. Silicone rubber is less thrombogenic than polyurethane. Polyurethane is thermoplastic, while silicone rubber is thermoset and does not soften at body temperature. Depending on the manufacturing process, the silicone rubber catheter may be made softer or harder, but is usually made soft. Most currently used catheters have dual lumens and are provided with a single polyester cuff. Most dual-lumen catheters have a beveled inflow bore and a few side holes for inflow. Almost all catheters are radiopaque or are provided with radiopaque stripe.

The catheters are inserted transcutaneously through the subclavian or jugular veins using a peel-away sheath method or surgically through the jugular vein into the superior vena cava or right atrium. Femoral veins are usually not used as a long-term access

for hemodialysis. Jugular veins serve as a primary insertion site, because complication rates associated with insertion through the subclavian veins are significantly higher.

Although historically the catheters were inserted with various approaches, currently the catheter is usually inserted through the Sédillot triangle (between the sternal and clavicular heads of the sternocleidomastoid muscle) using the Seldinger (Seldinger SI: Catheter replacement of needle in percutaneous arteriography; new technique. Acta Radiol 1953; 39: 368 - 376) method. In this method the vein is punctured with a large bore needle and a guide wire is inserted into the vein through the needle. The needle is withdrawn, the skin tunnel is created by a small incision, the entrance into the vein is prepared by a dilator. The subcutaneous tunnel is created with a trocar, the catheter is inserted through the tunnel and introduced into the vein using peel-away sheath. Then the tip of the catheter is advanced through the brachycephalic vein into the superior vena cava or right atrium. The surgical method is similar, with the exception that the incision over the Sédillot triangle is bigger and the vein is punctured under the direct vision.

There are two methods of subcutaneous tunnel creation. Because most catheters have an attached Y extension for connection with the dialyzer lines, the tunnel must be created from the skin exit to the site of the vein puncture (standard tunneling method). Another method, as described in my previous patents (US Patents 5,209,723; 5,405,320; and 5,509,897) requires that the

catheter be tunneled from the vein puncture site to the exit (reversed tunneling method). Such a method is possible if the Y extension is attached to the catheter **after** the catheter is pulled through the exit. In both methods the subcutaneous tunnel is created over the clavicle, thus the catheter in the tunnel has more or less a reversed "U" shape.

Mutatis mutandis, an insertion through the subclavian veins is similar to that through the jugular veins. The puncture of the subclavian vein is done just below the clavicle and slightly outside of the midclavicular line.

To prevent blood recirculation, most dual lumen catheters have inflow and outflow bores staggered approximately 2 cm, with outflow bore distal to that of inflow bore. Our studies (Twardowski ZJ, Van Stone JC, Haynie J: All currently used measurements of recirculation in blood access by chemical methods are flawed due to intradialytic disequilibrium and/or recirculation at low flow (Am J Kidney Dis; 1998; inpress) showed that at the high blood flow (over 300 mL/min) blood recirculation is only moderate, even in catheters with a flush tip. Various tip configurations aiming at decreasing clot formation were patented (US patents 5,509,897; 5,569,182; and 5,685,867).

Single Lumen Catheters

As mentioned above, for subclavian vein catheterization single lumen catheters were used in 1969 (Erben J, Kvasnicka J, Bastecky J, Vortel V: Experience with routine use of subclavian vein cannulation in hemodialysis. Proc Eur Dial Transpl Assoc 1969; 6: 59 - 64), a long time before two lumen catheters were

invented. Canaud et al. (Canaud B, Béraud JJ, Joyeux H, Mion C: Internal jugular vein cannulation using 2 silicone rubber catheters: A new, simple and safe long-term access for extracorporeal treatment. Nephron 1986; 43: 133 - 138. Canaud B, Béraud JJ, Joyeux H, Mion C: Internal jugular vein cannulation with two silicone rubber catheters: a new and safe temporary vascular access for hemodialysis. (Thirty months' experience. Artif Organs 1986; 10: 397 - 403.) They decided to continue the method of Erben et al. using two single-lumen catheters, but they changed material from polyethylene to silicone rubber and used jugular instead of subclavian vein insertion site. The catheters with inner/outer diameters of 2.0/3.2 mm had 6 side holes on the 5 distal centimeters. The catheters were exteriorized by reversed tunneling (from the cervical incision to the skin exit), and extension tubing adapters were attached to the catheters after their externalization. The catheters were not provided with cuffs.

An important advantage of single catheters is its smaller entrance into the vein and smaller exit site. With the smaller entrance it is more likely to cannulate the vessel repeatedly. The smaller exit is less prone to infections; however, infections were the most common complications of long-term jugular vein catheters (Canaud B. Leray H. Béraud JJ. Mion C. Acces vasculaire temporaire: du peripherique au central, du temporaire au permanent. [Temporary vascular access: from peripheral to central, from temporary to permanent]. Nephrologie. 1994; 15: 53-9.). It is worth stressing that these catheters were not provided with cuffs.

Tesio et al. (Tesio F. De Baz H. Panarello G. Calianno G. Quaia P. Raimondi A. Schinella D. Double catheterization of the internal jugular vein for hemodialysis: indications, techniques, and clinical results. Artif Organs. 1994; 18 :301-4.) used catheters very similar to those of Canaud. These were silicone rubber catheters with internal/external diameters of 2.0/3.2 mm and provided with 6 side holes on the 4 distal cm. Unlike Canaud catheters, Tesio catheters were provided with a 1 cm olive-like device to better fix the cannula in the tunnel by permitting some catheter longitudinal movement in the tunnel. A recent model of Tesio catheter is provided with a small cuff (2 mm wide) located on the olive-shape device. Tesio et al. (Tesio F, De Baz H, Panarello G. Successful Long-term Central Venous Access. Home Hemo Int. 1998; 2: 38 - 40) describe lower infection rates than that reported by Canaud et al.

Complications of Intravenous Catheters

There are two major complications of intravenous catheters: thrombosis and infection. Both are at least partly related to the catheter design.

Thrombosis

As early as in the mid 19th century, Rudolf Virchow postulated that three factors predispose to phlebothrombosis (clot formation in the vein): hypercoagulable state, vein wall damage, and blood stasis. These three factors are still judged to be the most important and have to be considered in planning preventive measures. With a foreign body in the blood vessel, an additional factor becomes important: the material from which this foreign body is made.

Measures Preventing Thrombosis

Thrombosis probably cannot be completely eliminated, but its incidence may be reduced by catheter design and appropriate anticoagulation. Only catheter design features decreasing thrombosis rates will be discussed here. These are: material, catheter shape and size, tip configuration, and number of lumens.

Material

Thrombogenicity of material is crucial in the speed of thrombus formation. Due to high thrombogenicity, prolonged catheterization was impossible with glass, polyethylene and polyvinyl cannulae. Polyurethane is claimed to be less thrombogenic than tetrafluoroethylene. In animal studies, silicone rubber catheters showed the lowest thrombogenicity compared to catheters made of other materials (Welch GW, McKell DW, Silverstein P, Walker HL: The role of catheter composition in the development of thrombophlebitis. Surg Gynecol Obstet 1974; 138: 421 - 442.). Silicone rubber is a preferred material to prevent catheter-related thrombosis.

Insertion site

The repeated damage to the intima seems to be crucial in thrombosis of cannulated veins. A strong argument for this mechanism is more frequent and massive thrombosis seen with left sided cannulation where the vein path is more tortuous (Ratcliffe PJ, Oliver DO: Massive thrombosis around subclavian cannulas used for hemodialysis (Letter). Lancet 1982; 1: 1472 - 1473.). In the series of Hoshal et al. (Hoshal VL Jr, Ause RG, Hoskins PA: Fibrin sleeve formation on indwelling subclavian central venous catheters. Arch Surg 1971;

102: 353 - 358.) mural thrombi usually formed at the points where the catheter pressed on the vessel wall, particularly where the tip touched on the intima. In choosing the insertion site these factors should be borne in mind. The jugular route, particularly on the right side, is advantageous since the course of catheter to the right atrium is almost a straight line, minimizing trauma to the intima. The path from the left jugular vein is more tortuous. Subclavian veins are least favorable because of tortuous course, particularly on the left side. Besides, the narrow space between the first rib and the clavicle, where the subclavian vein passes, predisposes to vein wall trauma when the catheter is squeezed by movement of the upper extremities. Cimochowski et al (Cimochowski GE, Worley E, Rutherford WE, Sartain J, Blondin J, Harter H: Superiority of the internal jugular over the subclavian access for temporary dialysis. Nephron, 1990; 54: 154 - 161.) stressed that vein stenosis is least likely if the stiff catheter is inserted through the right jugular vein. Schillinger et al. (Schillinger F, Schillinger D, Montagnac R, Milcent T: Post catheterization vein stenosis in hemodialysis: Comparative angiographic study of 50 subclavian and 50 internal jugular accesses. Nephrol Dial Transplant, 1991; 6: 722 - 724.) evaluated phlebographically the rate of stenosis of the subclavian and/or brachycephalic vein in cases cannulated previously through the subclavian route or through the jugular route. They found a stenosis in 42% of the subclavian group and in 10% of the jugular group. The right side was cannulated in 58% of cases in the subclavian group and 78% in the jugular group. The rate

of stenosis on the left side was higher, particularly in the jugular group (7.7% on the right and 18.2% on the left). It is worth stressing that the authors described the complications with use of stiff catheters.

Shape of the catheter

It is very likely that the major reason of these complications is pressure of the straight catheter on the vein intima at the "pressure points" where venous path takes a rapid turn. This led us to design a so-called "vein shape catheters", which has been patented (US patents 5,209,723; 5,405,320; 5,509,897; 5,569,182; and 5,685,867). The idea of these catheters is to make the shape of the catheter as similar as possible to the shape of vein where the catheter is located.

Side holes at the distal end

All catheters for acute hemodialysis are provided with side holes at the distal end. This is supposed to prolong catheter life, assuming that even if the distal bore is occluded by a clot, a few side holes may remain opened, providing sufficient blood flow. Most catheters for chronic dialysis, both single and dual lumen, are also provided with side holes. There are no data in support of the notion that side holes prolong the life of chronic catheters. The opposite is often true. Firstly, many times when removing chronic catheters, either electively or because of catheter obstruction, a clot is found attached to the tip of the catheter and anchored in the side hole of the inflow lumen. Such a clot is difficult to remove or dissolve while in situ. However, an intraluminal clot is usually easily removed or dissolved (Twardowski ZJ: High-dose intradialytic urokinase to restore the patency of permanent central

vein hemodialysis catheters. AJKD 1998; 31 (5): 841-847). The clot which is difficult to remove is formed on the outer surface of the catheter and extends to the inside lumen. Thus, the holes have no role in extending the life of the catheter. Also, the heparin solution, which is instilled to the catheter lumen at the end of dialysis, may not reach the catheter tip and may be leached out in the period between dialyses, thus predisposing to clot formation at the tip of the inflow lumen, especially when there are side holes. Finally, if the inflow bore is occluded and the blood flows through the side holes, it is likely that the vein intima is sucked into the holes, becomes damaged and causes formation of the clot in the vessel lumen. In such a case these holes would not be beneficial for the catheter life, but may be even precluding the possibility of inserting another catheter into the same vein at a later time.

Infections

There may be exit site/tunnel infection, sepsis, and septic thrombophlebitis.

Measures preventing infections

Infection rates may be decreased by catheter design, implantation technique and postimplantation care. Here I will concentrate on catheter features decreasing complications.

Material

Silicone rubber is a preferred material, because of its softness and hydrophobic (water repellant) properties.

Tunnel length

The length of the tunnel is dependent on the catheter length outside of the vein. The longer the tunnel the less likely it is for the microorganism to penetrate into the blood stream, but in a randomized prospective study, tunneling alone of uncuffed catheters was not found to decrease sepsis rates (von Meyenfeldt MM. Stapert J. de Jong PC. Soeters PB. Wesdorp RI. Greep JM. TPN catheter sepsis: lack of effect of subcutaneous tunneling of PVC catheters on sepsis rate. Jpen: J Parenter Enteral Nutr 1980; 4:514-7).

Cuffs

The cuff constitutes a significant barrier for periluminal bacterial penetration and the infection rates with the cuffed catheters are markedly lower than that with uncuffed catheters. There is no question that catheters without cuffs, both intravenous and peritoneal, are associated with very high infection rates and are not suitable for chronic use. Catheter related sepsis was found to be more than ten times higher with uncuffed catheters as compared to cuffed catheters in pediatric population (Rovner MS, Brouhard BH, Cunningham J, Firor H: Comparison of cuffed vs. uncuffed catheters for extracorporeal therapy in pediatric patients. Dialysis & Transplantation 1992; 21: 513 - 522) Although there are no data on the relationship between the number of cuffs and periluminal infection rates with intravenous catheter, such data exist for peritoneal catheters. A recent publication of the United States Renal Data System reported that compared to double-cuff catheter the risk of peritonitis was 16 and 31% higher for single deep-cuff and single

superficial-cuff catheters respectively. (U. S. Renal Data System, USRDS 1992 Annual Data Report, VI. Catheter-Related Factors and Peritonitis Risk in CAPD Patients. Am J Kidney Dis 1992; 5 (Suppl 2): 48 - 54). Our own study found that the peritonitis rates were lower with triple cuffed catheters compared to the double cuffed catheters (Twardowski ZJ, Prowant BF, Nichols WK, Nolph KD, Khanna R: Six-year experience with swan neck presternal peritoneal dialysis catheter. Abstracts of the XXXth Annual Meeting, San Antonio, Texas, November 2-5, 1997, Journal of the American Society of Nephrology 1997, 8:183A). Exit site infections were also found to be lower with cuffed catheters. Rovner et al. (Rovner MS, Brouhard BH, Cunningham J, Firor H: Comparison of cuffed vs. uncuffed catheters for extracorporeal therapy in pediatric patients. Dial Transplant 1992; 21: 513 - 522) reported an exit infection rate of 1.26/1000 days, with cuffed catheters compared with a rate of 4.85/1000 days with uncuffed catheters. A reason for higher infection rates with the absence of a cuff is poor immobilization of the catheter, which permits catheter movement outside the sinus where it collects contaminants and transfers them deep into the sinus after retraction. Also, catheter movement to and fro in the subcutaneous tunnel causes microtraumas predisposing further to infections.

Advantages and Disadvantages of Dual Lumen Catheters

A main advantage of dual lumen catheters is convenience of insertion. Instead of two punctures only one puncture is required. This cut the insertion time by half and decreased complication rates related to the insertion procedure itself. This feature was very

important when stiff catheters for acute dialysis were used because the catheter was inserted for only a few days. For chronic dialysis this feature is almost irrelevant, because the catheters are used for several months or years and decrease of thrombotic and infectious complications takes precedence over convenience and complication rates during insertion. Besides, complication rates during insertion of soft catheters is very low.

The main disadvantage of dual catheters is their large diameter. The larger diameter, the more damage to the vessel wall and the higher exit-site infection rates. As mentioned above, compared to a single lumen catheter, the dual lumen catheter is stiffer at the same durometer (hardness) of material. Consequently the damage to the pressure points (see above) is more pronounced.

Disadvantages of Single Lumen (Canaud and Tesio) Catheters

A major advantage of single lumen catheters resides in their smaller diameter and better flexibility. This decreases damage to the vessel wall, vein intima, and decreases exit site infection rates.

The major disadvantage of the Canaud catheter is the lack of a cuff. A cuffless catheter is associated with high infection rates as explained above. The Tesio catheter is provided with an olive-shape device on which a small cuff is located. The olive shape device and a small cuff permits an easy removal of the catheter out of the tunnel in case of the need for replacement; however, such a design leads to frequent spontaneous cuff extrusions and/or catheter dislodgement. A single,

small cuff is not a strong barrier against penetration of microorganisms into the blood stream. Also, the olive shape device permits the catheter to move longitudinally back and forth over a small range, which promotes vein damage and infection.

Side holes at the catheter tip predispose to clotting for the reasons described above.

Accordingly, there is a need for a catheter which exhibits less blood vessel wall damaging capability, and which exhibits less potential for infection, as well as reduced clotting capability. A catheter having the above characteristics is provided by this invention.

DESCRIPTION OF THE INVENTION

By this invention, a single-lumen, flexible, implantable catheter is provided for permanent access to the vascular system of a patient. The catheter has proximal and distal ends, being free of side holes adjacent to the distal end. Thus, clotting tendencies which are promoted by such holes are eliminated.

The catheter of this invention carries at least two spaced tissue attachment cuffs adjacent to its proximal end. The cuffs are of a type that provides substantially immoveable attachment of the catheter to surrounding tissue for example, the "olive shape" structure is not used.

Thus, the catheter of this invention, when fully grafted into positioned by growing tissue, is resistant to longitudinal movement. This, in turn reduces both vein wall damage, and reduces the tendency for infection caused by the longitudinally moving catheter driving

bacteria inwardly from the vicinity of the skin into the tissue tunnel. The cuffs that are preferably used generally comprise a cylinder of fabric attached to the catheter, and are conventionally known.

Preferably, the catheter may be made of a hemocompatible silicone rubber or equivalent material such as some polyurethanes, to provide a minimum clotting effect of the blood by the catheter material. Also, it is preferred for the catheter to have an outer diameter of essentially no more than 4.5 mm., less than conventional double lumen hemodialysis catheters, with the result that both the tendency to infection and the tendency to vein wall damage is reduced by the reduced diameter of the catheter. The diameter of the lumen may be about 2-3 mm.

In this invention, the catheters for long-term hemodialysis access are intended to be inserted into the superior vena cava or right atrium typically through one of the following veins:

1. Right internal jugular vein
2. Right external jugular vein
3. Left internal jugular vein
4. Left external jugular vein
5. Right subclavian vein
6. Left subclavian vein

For intermediate-term blood access, the catheter can be inserted into the common iliac vein or inferior vena cava through the left or right femoral vein.

The intravenous catheter of this invention comprises a flexible catheter body, which contains only one lumen for inflow or outflow of the blood. The body has a proximal and distal end portion. The distal end

portion connects to a vein of a patient. The proximal end portion normally connects in use to a tubular extension set, which may be coupled with any blood processing and/or intravenous fluid delivery system, such as a hemodialyzer, hemofilter, plasmapheresis apparatus, etc.

The catheter is provided also with preferably at least two cuffs (subcutaneous or external and deep or internal), which are typically bands of fabric affixed to the catheter body (tubing) for fibrous tissue ingrowth in the catheter tunnel.

Implantation of the catheter may be performed either surgically in an operating room or in a procedure room under sterile conditions. After anesthetizing the skin over the intended insertion site, a small, 1 - 3 cm skin incision is made and dissected bluntly closer toward the vein. The Seldinger (Seldinger SI: Catheter replacement of needle in percutaneous arteriography; new technique. Acta Radiol 1953; 39: 368 - 376) method of catheter insertion, already described above, is a preferred method of catheter insertion into the vein. The catheter tip is positioned in the desired location with the help of fluoroscopy. A proximal end portion is then used as a gauge to mark the positions of the external cuff and the exit. Using a small hemostat or other suitable instrument a tunnel is made from the incision to the level where the external cuff will lodge. A trocar with the external diameter identical to the catheter tubing is attached to the external end of the catheter, passed through the exit site and the catheter is pulled through the exit. An extension set is then attached to the catheter and the catheter is

covered with immobilizing dressing. Because the external cuff is preferably bigger then the last portion of the subcutaneous tunnel, the catheter cannot dislodge outside. Thus no anchoring suture is needed at the exit site.

Relative to the human body after the implantation the catheter consists of three segments: **1) intravenous catheter segment** is the part of the catheter located intravenously; **2) intramural catheter segment** is the part of the catheter contained within the tunnel; and **3) external catheter segment** is the part of the catheter outside the skin exit. **The catheter tunnel** is the passageway through the thoracic wall within which the catheter is contained. **Internal tunnel exit** is the inlet of the tunnel into the vein. **Skin exit** is the skin outlet of the tunnel. The **Subcutaneous or superficial or outer or external cuff** is located close (1 - 3 cm) to the skin exit. **The second inner or deep cuff** is located 2 - 6 cm from the external cuff, closer to the vein. The part of the tunnel between the skin exit and the outer cuff constitutes the **sinus tract.**

The catheter may be made radiopaque by addition of barium sulfate or other suitable material into the catheter body. This will facilitate visualization of the catheter on an X-ray.

The subcutaneous cuff provides both a bacteriological barrier against tunnel infection and anchoring means of the intramural and external catheter segments, minimizing the movement of the catheter into and out of the tunnel. As mentioned above, such a movement predisposes to contamination of the tubing with introduction of contaminants into the sinus tract

(catheter tunnel) after its retraction. A downwardly directed skin exit catheter portion further decreases chances of sinus tract contamination with the down-flowing sweat and bacteria laden water. Also, a downward directed exit facilitates pus drainage, should infection occur.

The external segment of the catheter protrudes a few centimeters out of the skin, and is attached to an extension set comprising a connector having a flexible extension tube, approximately 7 centimeters in length and equipped with a female Luer lock adapter and sealing cap. The external extension tube set is attached to the catheter body after the catheter is inserted into the vein and the subcutaneous tunnel is created. During the connection procedure for fluid delivery and/or blood egress, the extension tube is clamped, the cap is removed, and an appropriate male Luer adapter is coupled with the Luer lock adapter of the extension tube. After prolonged use, the extension tube set may be damaged to the extent that it has to be replaced. The catheter external set connector facilitates the replacement without the necessity of the catheter removal.

One catheter only may be needed for drug delivery, parenteral nutrition, and blood withdrawal for repeated laboratory tests. Although one catheter may also be used for blood purification procedures (hemodialysis, plasmapheresis, hemofiltration, etc) two catheters are preferred there, one for inflow and one for outflow on a continuous basis. If two catheters are inserted, the tips of the catheters should preferentially be a few centimeters apart with the outflow closer to the right atrium. Two catheters may

be inserted through the same vein or through two veins. Any combination of insertion sites may be used, e.g., one catheter through the right external jugular vein and the other through the left subclavian vein.

DESCRIPTION OF THE DRAWINGS

Fig. 1 is a plan view of one embodiment of a catheter of this invention;

Fig. 2 is an enlarged, perspective view, with the central portion broken away, of the catheter distal end and also the catheter cuffs near the proximal end;

Fig. 3 is a longitudinal sectional view of the catheter proximal end, shown to be attached to a removable extension tube;

Fig. 4 is an enlarged, fragmentary view of the proximal catheter end, shown to be connected to the distal end of a metallic trocar;

Fig. 5 is a perspective view showing how a catheter of this invention may have its proximal end placed through a tissue tunnel during installation, with the motion of installation being outwardly through the skin, all prior to addition of the extension tube on the proximal end of the catheter;

Fig. 6 is an elevational view showing how two catheters can be installed in separate tissue tunnels of a patient into the left internal jugular vein, to

terminate at their distal ends in the right atrium of the heart; and

Figs. 7 is an elevational view showing a alternative implantation scheme of a catheter pair in a patient in separate veins, to reach the right atrium of the heart.

DESCRIPTION OF SPECIFIC EMBODIMENTS

Whereas this invention may have embodiments in many different forms, in the drawings is shown and will herein be described in detail currently preferred embodiments of the invention.

Fig. 1 is a plan view of the catheter of this invention. The catheter comprises body 10, a deep cuff 12, and a subcutaneous cuff 14. The catheter body has an intravenous distal end or tip 16 and an external proximal end 18.

Fig. 2 is an enlarged view of the catheter distal end 16, and an enlarged view of the catheter cuffs 12, 14 as they are attached to the catheter body. There are no side holes at the catheter tip 16 or anywhere else on the catheter. The two cuffs 12, and 14 near the proximal end 18 of the catheter are spaced about 2 - 6 cm. from each other. Distal end 16 comprises a flat, circular surface 17, perpendicular to the tube axis.

Fig 3. shows the external, proximal end 18 of the catheter, attached through a barbed connector 20 to an external tube set 22 comprising flexible extension tube 24, female Luer lock adapter 26, and sealing cap 28. The barbed connector 20 has an internal lumen 21, and

may be made of any stiff, biocompatible material, like polytetrafluoroethylene. The internal diameter of connector 20 of tube 24 should preferably be about identical to that of the catheter body 10. The connection is reinforced by a sleeve 30 glued to the catheter body 10 on one side and the extension tube 24 on the other side. See Twardowski et al. U.S. Patent No. 5,509,897, Figs. 5 and 6.

Fig. 4 is an enlarged view of a trocar 32 attached to the external proximal end 18 of catheter 10, prior to attaching external set 22.

Fig. 5 shows the method of creating a subcutaneous tunnel using the trocar 32 attached to catheter 18, forming and passing through the tunnel 33 and the skin exit site 34. To do this, an incision 35 is formed in the skin of the patient, through which the distal end portion 16 of catheter 10 is inserted into the vein of the patient. In the same procedure, trocar 32 passes through the wall of incision 35 to form tunnel 33 through tissue of the patient, terminating at tunnel exit 34 at the skin of the patient. Trocar 32 is advanced through exit site 34, drawing the proximal end 18 of catheter 10 with it until the catheter is positioned in the desired manner. This basically known technique permits the emplacement of the catheter with an outward motion through the skin, which prevents bacteria from being drawn into tunnel 33.

Fig. 6 shows two catheters of this invention as they may preferably be implanted by the above-described technique into the right atrium through the left internal jugular vein. Each catheter is labeled with a number and subscript "$_i$" for the inflow catheter and

subscript "$_o$" for the outflow catheter. The inflow catheter 10_i consists of three segments: intravenous 34_i, located in the vein, intramural 36_i, located in the tunnel, and external 38_i, located outside of the skin exit 40_i. The extension set 22_i is also shown. The outflow catheter 10_o consists of identical three segments: intravenous 34_o, located in the vein, intramural 36_o, located in the tunnel, and external 38_o, located outside of the skin exit 40_o. The extension set 22_o is also shown.

The Fig. 6 emplacement permits the simultaneous high volume administration and withdrawing of blood for a hemodialysis procedure, or some other blood treatment procedure, as may be desired. The catheters 10_i , 10_o of this invention may have an outer diameter of about 3 - 4 mm., substantially less than the respective outer diameters of dual lumen catheters which have been used as permanently implanted hemodialysis catheters. Because of this reduction in outer diameter, less vein wall damage and less tendency for infection can be provided.

In Fig. 7 catheters 10_i and 10_o, of similar design, purpose, and use to the corresponding catheters of Fig. 6, are shown to be separately implanted in two separate veins, in those cases where such separation of the catheters is deemed to be clinically advantageous. The results achieved are the same as in the previous embodiment.

Also, the catheters of this invention exhibit less clot formation, being free of side holes, and less tendency toward tunnel infection because of the presence of the respective cuffs 12, 14, which cuffs are of the

type that firmly hold the catheter to the surrounding tissue when the implantation has fully healed, so that the catheter does not exhibit any longitudinal pumping action or other motion relative to the tunnel.

Because of the reduction in clotting characteristics and also because of the reduction of infections, the catheters of this invention may be implanted and exhibit trouble free, longer catheter survival than catheters of the prior art.

The above has been offered for illustrative purposes only, and is not intended to limit the scope of the invention of this application, which is as defined in the claims below.

THAT WHICH IS CLAIMED:

1. A single-lumen, flexible, implantable catheter for permanent access to the vascular system of a patient, said catheter having proximal and distal ends, said catheter being free of side holes adjacent to said distal end, said catheter carrying at least two spaced tissue attachment cuffs adjacent to said proximal end, said cuffs being of the type that provides substantially immovable attachment of the catheter to surrounding tissue.

2. The catheter of claim 1 which comprises a hemocompatible silicone rubber.

3. The catheter of claim 1 which has an outer diameter of essentially no more than 4.5 mm.

4. The catheter of claim 3 in which said proximal end is attached to a trocar.

5. The catheter of claim 3 in which said proximal end is connected to a removable extension tube.

6. The catheter of claim 1 in which said distal end comprises a flat surface substantially perpendicular to the tube axis.

7. The catheter of claim 1 in which said proximal end is attached to a trocar.

8. The catheter of claim 1 in which said

proximal end is connected to a removable extension tube.

9. The method of emplacing a single-lumen, flexible, implantable catheter for permanent access to the vascular system of a patient, said catheter having a distal end free of side holes and carrying at least two spaced tissue attachment cuffs adjacent to a proximal end opposed to said distal end, which method comprises:

making an incision in a patient adjacent to a vein for catheter installation; installing said distal end and a portion of said catheter adjacent to said distal end in the vein; passing a trocar attached to the proximal end of said catheter from an internal wall of said incision through tissue to exit through the skin of the patient and form a surgical tunnel; drawing the catheter through said surgical tunnel made by said trocar until the proximal catheter end projects through the skin; and closing said incision.

10. The method of Claim 9 in which said trocar is removed from the catheter proximal end, and an extension tube is attached to said catheter proximal end.

11. The method of Claim 10 in which said catheter has an outer diameter of no more than essentially 4.5 mm.

12. The method of Claim 11 in which said catheter comprises a hemocompatible silicone rubber and said distal end comprises a flat surface substantially

perpendicular to the tube axis.

13. The method of Claim 12 in which said cuffs are of the type that provides substantially immoveable attachment of the catheter to surrounding tissue.

14. A single lumen, flexible, implantable catheter for permanent access to the vascular system of a patient, said catheter comprising a hemocompatible silicone rubber and having an outer diameter of no more than essentially 4.5 mm., said catheter having proximal and distal ends, said catheter being free of side holes adjacent to said distal end, said catheter carrying at least two spaced tissue attachment cuffs adjacent to said proximal end, said cuffs being of the type that provides substantially immoveable attachment of the catheter to surrounding tissue.

15. The catheter of Claim 14 in which said distal end comprises a flat surface substantially perpendicular to the tube axis.

16. The catheter of claim 15 in which said proximal end is connected to a removable extension tube.

17. The catheter of Claim 15 in which said proximal end is attached to a trocar.

18. The catheter of claim 14 in which said proximal end is connected to a removable extension tube.

19. The catheter of Claim 14 in which said

proximal end is attached to a trocar.

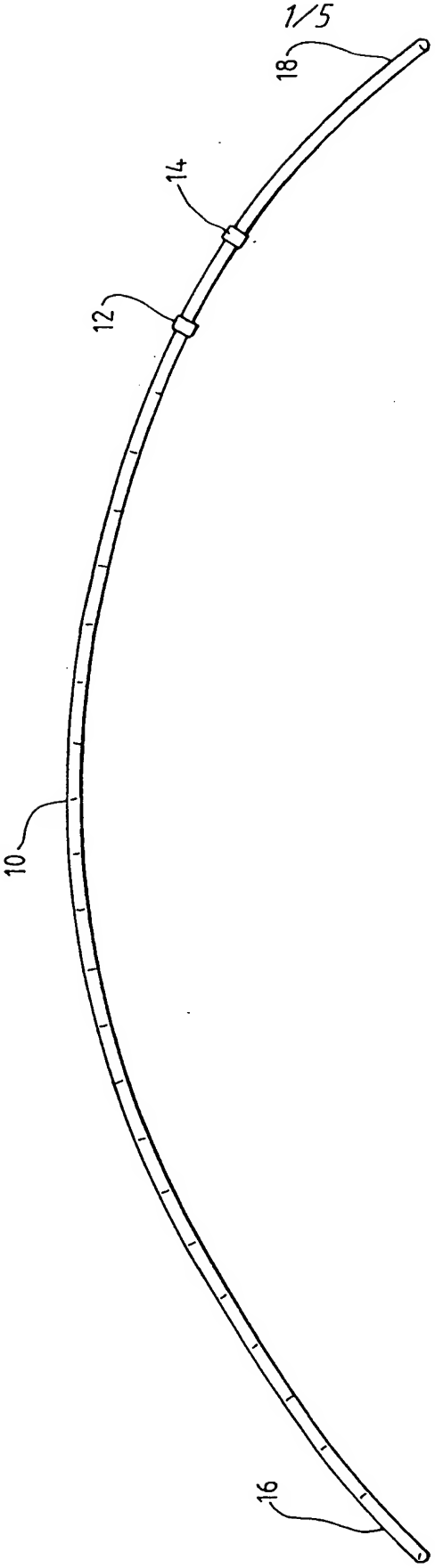


FIG. 1

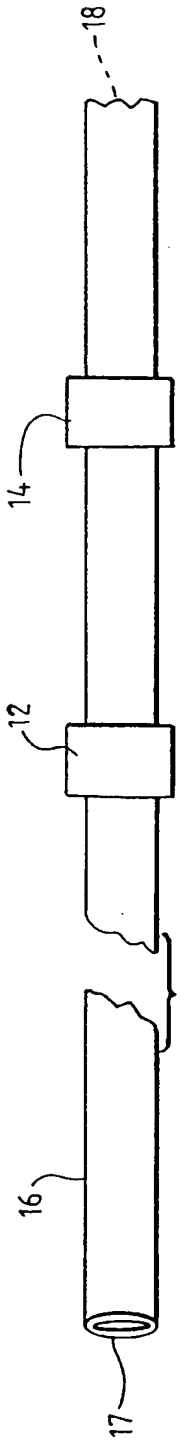


FIG. 2

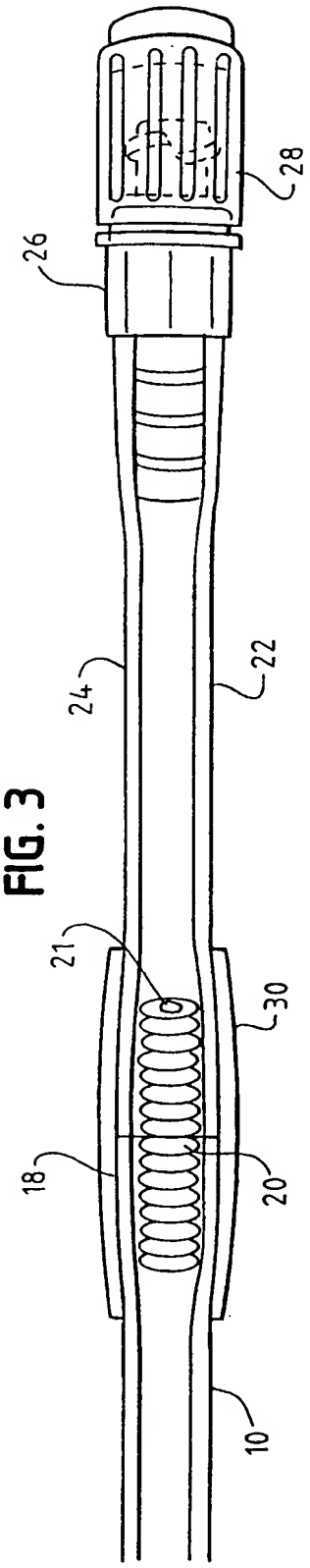


FIG. 3

FIG. 5

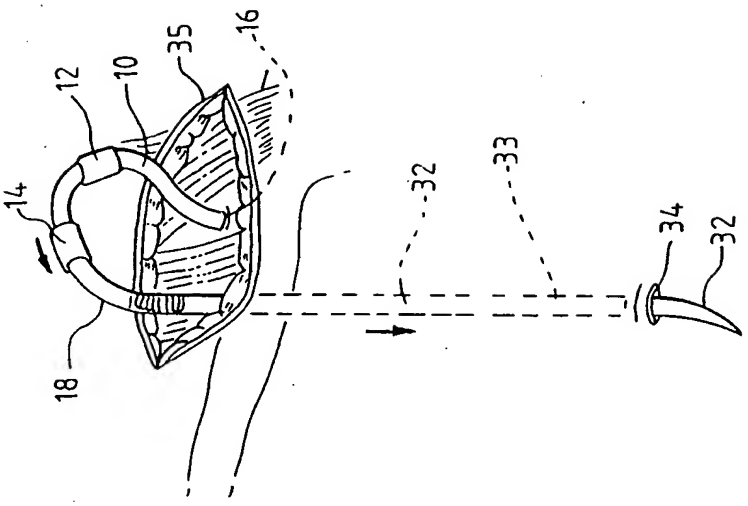
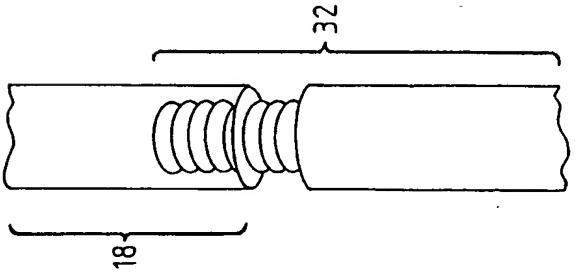


FIG. 4



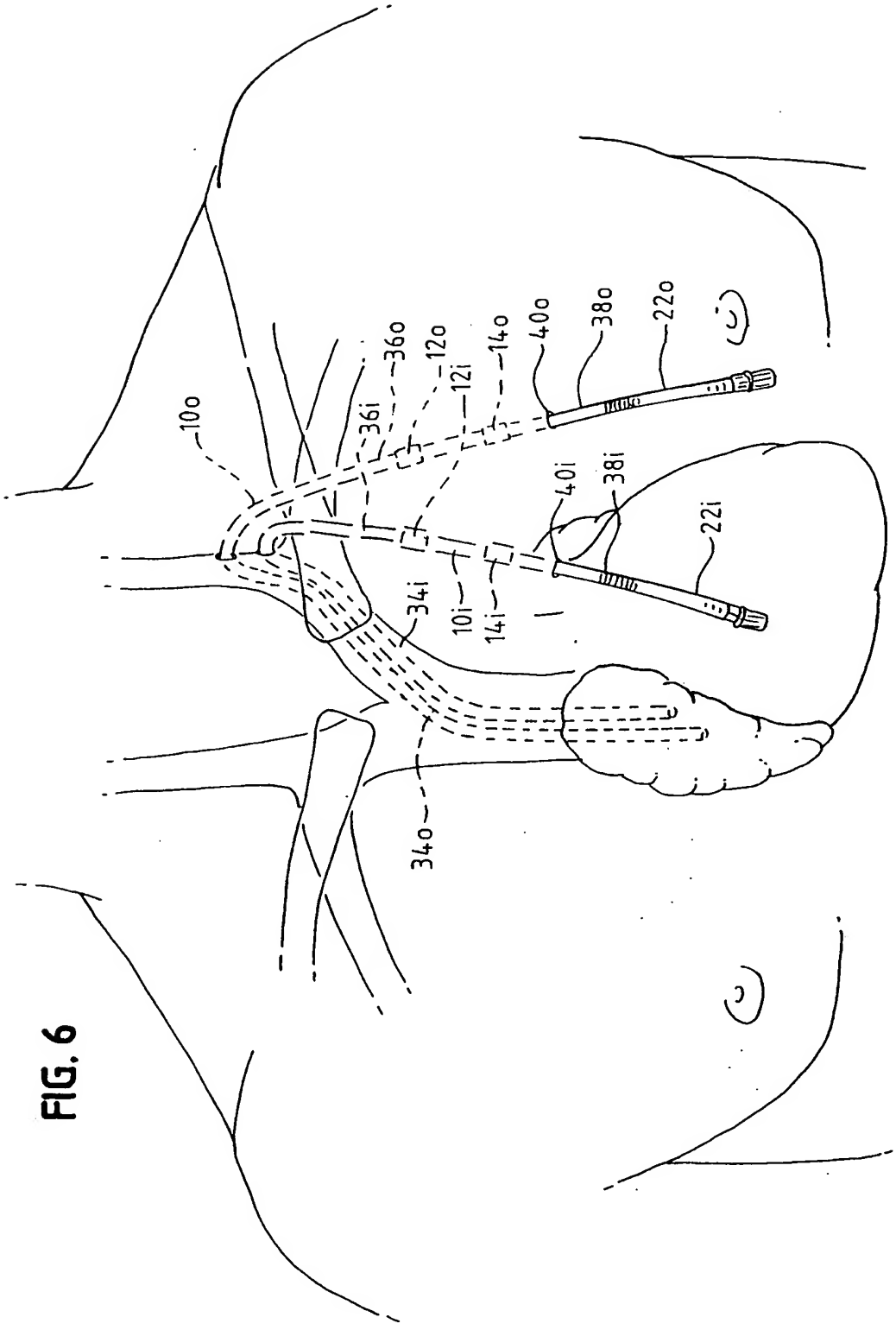


FIG. 6

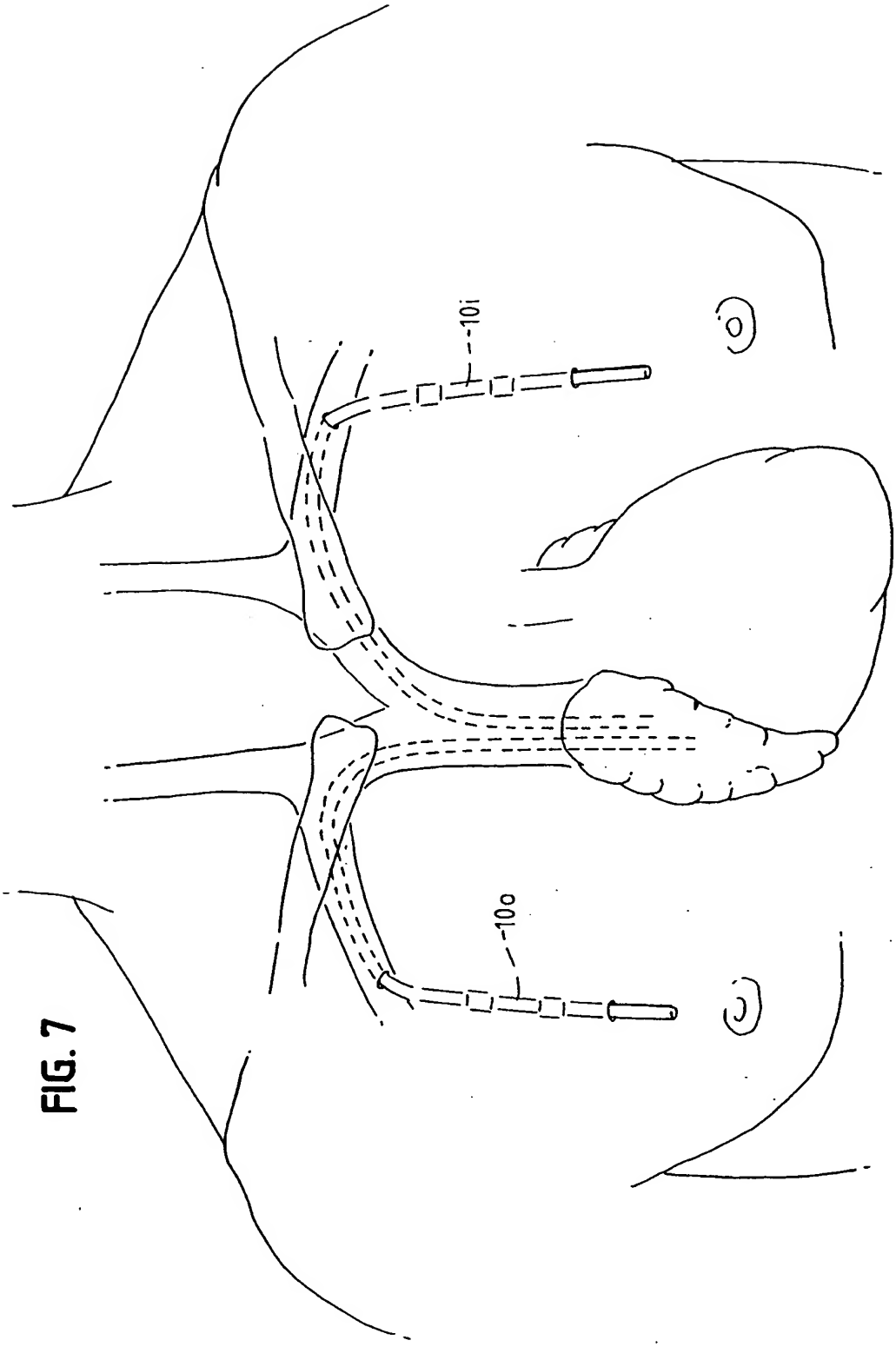


FIG. 7

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US99/21667

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) :A61M 29/00
US CL :604/101

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 604/93, 96, 101, 264, 266, 523

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X --- Y	US 5,509,897 A (TWARDOWSKI et al.) 23 April 1996, elements (124)(126), col. 6 line 7, col. 10 line 43, col. 4 lines 48-57, Fgs. 1, 5, and claim 4.	1, 2, 6-8 --- 3-5, 9-19
A	US 5,156,592 A (MARTIN et al.) 20 October 1992, entire patent.	1-19
A	US 5,053,023 A (MARTIN) 1 October 1991, entire patent.	1-19
A	US 4,772,269 A (TWARDOWSKI et al.) 20 September 1988, entire patent.	1-19

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

*	Special categories of cited documents:	"T"	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"A"	document defining the general state of the art which is not considered to be of particular relevance	"X"	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"E"	earlier document published on or after the international filing date	"Y"	document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"L"	document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"&"	document member of the same patent family
"O"	document referring to an oral disclosure, use, exhibition or other means		
"P"	document published prior to the international filing date but later than the priority date claimed		

Date of the actual completion of the international search 05 DECEMBER 1999	Date of mailing of the international search report 04 FEB 2000
Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703) 305-3230	Authorized officer JEREMY THISSELL Telephone No. (703) 305-5361

Form PCT/ISA/210 (second sheet)(July 1992)*